

Applicants: Adams et al.  
Application No. 10/591,369  
Amendment and Response dated March 15, 2010  
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### **REMARKS/ARGUMENTS**

The application has been amended. Entry of the amendments and reconsideration are respectfully requested.

### **Status of the Claims**

Claims 1-25 are pending in the application prior to entry of the amendments herein. Claims 17-25 have been withdrawn from consideration as drawn to non-elected subject matter.

### **Discussion of the Amendments to the Claims**

The claims have been amended to more particularly point out and distinctly claim the subject matter of the present invention. In particular, claim 1 has been amended to recite that from 0.1 to 50% by weight of the mixture is amorphous and to recite that where the excipient is crystalline, it is selected from a eutectic salt, glycine, mannitol and sorbitol. Moreover, claim 1 has been amended to recite that where the excipient is amorphous, it is selected from glutamine, serine, a monosaccharide, a disaccharide, a trisaccharide, a polysaccharide, polyethylene glycols having a molecular weight of about 6000, a polyamino acid, poly-d-lactic acid, amorphous lactose, a polyethylene glycol having a molecular weight up to 1000, a polyglycan, a polysaccharide, a cyclodextrin, povidone, micro-fine cellulose, potato starch and a protein. Also, claims 2-5, 8 and 14 have been amended to delete certain language as shown herein. New claims 27-30 have been added. Support for the amendments to the claims may be found at, for example, page 6, line 26 to page 7, line 20, the examples, at page 13, lines 21-29, and at original claim 1. No new matter has been presented by way of the amendments to the claims.

### **Response to the Rejection under 35 U.S.C. §112, Second Paragraph**

Claims 1-16 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. In particular, the Examiner has alleged that "[a] broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same

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claim) is considered indefinite.” (Office Action, pages 3-8). Reconsideration is respectfully requested in view of the amendments and remarks herein.

Claims 1-5, 8, and 14 have been amended herein. Applicants respectfully submit that the amendments to claims 1-5, 8, and 14 render the rejection with regard to those claims moot.

Claims 6-7, 9-13, and 15-16 all depend directly or indirectly from claim 1. Applicants respectfully submit that the amendments to claim 1 obviate the basis for the rejection with regard to claims 6-7, 9-13, and 15-16.

In view of the foregoing, withdrawal of the rejection under 35 U.S.C. §112, second paragraph, with regard to claims 1-16 is respectfully requested.

**Response to the Rejection under 35 U.S.C. §102(b)**

Claims 1, 2, and 6-16 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by WO 02/101412 A2 to Maa (Maa), as evidenced by Surana, Pharm. Res., Vol. 21, No. 7, July 2004 (Surana). Reconsideration is respectfully requested in view of the amendments and remarks herein.

Claim 1 has been amended to recite that from 0.1 to 50% by weight of the mixture is in an amorphous state and to recite that where the excipient is crystalline, it is selected from eutectic salt, glycine, mannitol and sorbitol. Moreover, claim 1 has been amended to recite that where the excipient is amorphous, it is selected from glutamine, serine, a monosaccharide, a disaccharide, a trisaccharide, a polysaccharide, polyethylene glycols having a molecular weight of about 6000, a polyamino acid, poly-D-lactic acid, amorphous lactose, a polyethylene glycol having a molecular weight up to 1000, a polyglycan, a polysaccharide, a cyclodextrin, povidone, micro-fine cellulose, potato starch and a protein.

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Maa fails to disclose a powdered formulation as recited in amended claim 1. In particular, Maa fails to disclose or suggest formulations where from 0.1 to 50% by weight of the mixture is in an amorphous state and which include an excipient as recited in amended claim 1. Rather, the formulations in Maa have over 50% by weight of amorphous material or do not have an excipient as recited in amended claim 1. As Maa fails to disclose each and every element of claim 1 as amended herein, Maa fails to anticipate amended claim 1.

Claims 2 and 6-16 all depend either directly or indirectly from claim 1. Accordingly, Maa fails to anticipate the subject matter of claims 2 and 6-16 for the same reasons discussed above with respect to claim 1. Indeed, Maa fails to disclose each and every element of claims 2 and 6-16 as presented herein.

Surana is merely relied on by the Examiner as teaching that freeze-drying or spray-drying gives an at least partially amorphous product. Surana fails to disclose each and every element of claims 1-2 and 6-16. As such, Surana fails to anticipate the subject matter of claims 1-2 and 6-16.

In view of the foregoing, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §102(b) of claims 1-2 and 6-16 in view of Maa as evidenced by Surana.

**Response to the Rejection under 35 U.S.C. §103(a)**

Claims 1-16 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Maa, WO 02/101412 A2 (Maa), as evidenced by Surana, Pharm. Res., Vol. 21, No. 7, July 2004 (Surana). Reconsideration is respectfully requested in view the amendments and remarks herein.

Claim 1 has been amended to recite that from 0.1 to 50% by weight of the mixture is in an amorphous state and to recite that where the excipient is crystalline, it is selected from

eutectic salt, glycine, mannitol and sorbitol. Moreover, claim 1 has been amended to recite that where the excipient is amorphous, it is selected from glutamine, serine, a monosaccharide, a disaccharide, a trisaccharide, a polysaccharide, polyethylene glycols having a molecular weight of about 6000, a polyamino acid, poly-d-lactic acid, amorphous lactose, a polyethylene glycol having a molecular weight up to 1000, a polyglycan, a polysaccharide, a cyclodextrin, povidone, micro-fine cellulose, potato starch and a protein.

Maa fails to disclose or suggest a powdered formulation as recited in amended claim 1. In particular, Maa fails to disclose or suggest formulations where from 0.1 to 50% by weight of the mixture is in an amorphous state and which contain excipients as recited in amended claim 1.

Moreover, there is no teaching in Maa about the stabilization of a free-dried composition by reducing the hygroscopicity. Maa is directed to a spray freeze-dried composition which has a sufficient density to be administered by a needleless syringe. In particular, Maa states at page 26, lines 19-24, that the excipients are selected to "allow the particles to collapse and densify during freezing and therefore provide powders which are particularly suitable for injection via a needleless syringe". Therefore, the teaching of Maa is different from the present invention as defined by the pending claims, and there is nothing in Maa which suggests the present invention as defined by the pending claims.

Moreover, Surana does not overcome the deficiencies of Maa. Indeed, the Examiner has not even discussed Surana in the rejection under 35 U.S.C. §103(a).

Claims 2-16 all depend either directly or indirectly from claim 1. Accordingly, claims 2-16 are not obvious in view of Maa and Surana for the same reasons discussed above with respect to claim 1. Indeed, there is no disclosure or suggestion in Maa or Surana of the subject matter of claims 2-16.

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In view of the foregoing, Applicants respectfully submit that claims 1-16 are not obvious in view of the cited combination of Maa and Surana. Accordingly, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §103(a) in view of Maa and Surana.

**Concluding Remarks**

An allowance of the claims is respectfully requested. Should the Examiner have any questions or comments concerning the foregoing, the Examiner is respectfully invited to contact the undersigned at the telephone number given below.

The Commissioner is hereby authorized to charge payment of any fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R.

§ 1.17 and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. § 1.136.

Respectfully submitted,



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